**SYRINGES** 

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## 09/486549 SAFETY BOX/INCINERATION CONTAINER FOR USED

The invention concerns a secure box/ combustion container, which forms the so-called "POLYSAFE SAFETY BOX" product system for temporary and secure safekeeping of, in particular contagious, surgical waste material in the form of used one-time injection syringes and needles for syringes, used dressing material and similar goods, with a view to subsequent

transportation for destruction or combustion.

This type of material may be contaminated, for instance by way of contaminated blood, and forms a considerable hazard for all personnel which come into contact with the material, not least due to the risk of being exposed to HIV and AIDS contagion, if the used material is not treated in a safe way. The World Health Organisation, WHO, has estimated that about one billion injections per year are performed only in so-called developing countries. Blood contagion may, in this connection, be spread through re-use of contaminated one-time syringes and needles, as well as through careless contact with contaminated dressing material.

It is often claimed that containers and similar goods for temporary storage of used syringes, dressing material etc. must be in compliance with international regulations as specified in BS3720:1990; Sharps Containers, which has been issued for keeping potentially hazardous medical waste, mainly consisting of surgical equipment, for instance scalpel blades, hypodermic needles and syringes which may easily cause bodily harm. BS3720 lay down rules for constructional details, such as handle and opening cover, the container material's durability against penetration, and the material's qualities in combination with the container construction for prevention of significant deformation caused by falling and turning over. This has caused the said standard only being applied to use of products made from plastic. In addition, it is required that markers are used in the form of special labels. Due to the high cost of manufacturing and transportation, as well as the risk for environmental pollution by destruction of the contents of the container, as well as unwanted use of non-reusable resources; other solutions are frequently selected, often without considering the necessary safety precautions, by for instance preliminary storage of contagious waste materials in other containers or buckets with covers, or boxes made from non liquid proof corrugated paper, and

which in turn therefore must be wrapped in relatively thick plastic bags. Both these types of storage are costly as well as space consuming.

Containers made from other, suitable and undefined materials is possible, and these may work better than plastic containers, and are made in accordance with WHO performance specification ET/IC2, which main reference still is PS7320, and which in addition requires being waterproof, as well as a simple, convenient and problem free with respect to assembly and mounting. WHO Performance Specification ET/IC.1 further specifies a strict requirement, requiring the container to accommodate complete combustion of used syringes etc., without loss of contents, and which may preferably be used rather then the above-mentioned plastic containers and –buckets with covers or boxes made from corrugated paper.

Based on the aforementioned views, being mentioned in which is a safety box /combustion container of a new and approved type, for temporary and risk-free storage, especially of possible contagious surgical material, mainly in the form of used syringes and injection needles, used dressing materials and similar goods, with a view for subsequent transportation for destruction or combustion.

This has been achieved through producing a safety box/ combustion container, type GLO1.5 according to the invention, and which is further described below, and which forms part of the above-mentioned "POLYSAFE SAFETY BOX" product system, and which is characterised in the subsequent patent claim. In order to handle contagious material, plastic containers or – buckets with covers are used today. These containers which are mainly used in industrialised country, are not cost effective in use, due to poor utilisation of space, and considerable transport costs. Light waste, for instance contaminated dressings etc. are often stored in boxes made from corrugated paper. These boxes are not fluid proof, and must be rapped in relatively thick plastic bags or the like. Both of these storage methods are rather costly.

EP 0 328416, A1 deals with a disposable enclosed container erected from a blank of a foldable material, whereinto disposable discarded surgical articles may be temporarty stored for subsequent destruction/combustion. Scorelines divide the blank into a plurality of plates which may be folded around the scorelines to erect the closed container, where the container sides consist of a multilayered corrugated material which, in contrast with the safety box of

the present invention, is laminated with a coating on the outside and a metal foil on the inside. Contrary to the present invention, contiguous container sides are glued together in stead of jointed by means of locking flaps that are pushed into mating slits. A detachable cover leaf (T) as with the safety box of the present invention, which may be set on fire and inserted into the container, for combustion of this with the waste contents, is neither discussed nor depicted.

In US-Pat. 4452 358, A1 there is described and shown a disposable container with at least one opening for inserting used and discarded surgical articles for subsequent removal and destruction. The discussed and depicted container is, contrary to the safety box of the present invention, provided with means, detailed shown and described, for bending or shearing used and discarded syringe needles and in this way preventing inadvertent reuse of these articles. This seems to be a fundamental feature of said container. Scorelines divide the container blank into coherent plates which may be folded around the scorelines for erecting the completed container. The foldable plates forming the container sides are neither discussed nor depicted joined together by means of locking flaps pushed into mating slits, and not a detachable cover leaf (T) as with the safety box of the present invention, which may be set to fire and inserted into the container, for combustion of this with the waste contents.

US-Pat. 4674676, A1 deals with a disposable container for temporary storing of surgical articles, used and discarded, for subsequent destruction. In contrast with the present invention, the container has an outer closure flap with is glued to the inside of the contigous backplate, for partly erecting the completed container. A detachable closure flap (T) as with the safety box of the present invention, which may be incinerated and inserted into the container, for combustion of this with the waste contents, is neither discussed nor shown.

US-Pat. 5039004, A1 deals with a disposable container for temporary storing of surgical articles, used and discarded, for subsequent destruction. The container is made from a blank of fibre material, divided into coherent plates, that are glued together, contrary to the safety box of the present invention, which is held together by locking flaps that are pushed into mating slits. A detachable closure flap (T) as with the safety box of the resent invention, which may be incinerated and inserted into the container, for combustion of this with the waste contents, is neither discussed nor depicted.

The invention is thoroughly discussed with reference to the enclosed drawings, where

Figure 1	shows the safety box / combustion container according to the invention,
	as assembled.
Figure 2	shows an enlarged plan view of an unfolded material with pressed

folding lines for making of the container according to figure 1.

Figures 3 to 8 shows the combustion development after 1, 3, 6, 12, 17 and 20 minutes, respectively.

Figure 9 shows in five different plan views the mounting of the safety box / combustion container according to the invention, by making and folding of a flat material around pressed folding lines.

The waste container 12 as shown in figure 1 is made from a laminated, largely flat material 10 with a number of flaps, which when folded around pressed folding lines, will form a finished container 12, ready for use. The container 12 is made by folding flap A approximately 90 °C around folding line a towards flap B, which again is folded approximately 90 °C around folding line b towards flap C, and flap D is folded approximately 90 °C around folding line c towards flap C, and the rim section D' is folded around the folding line D and glued to the lower part of flap A. Flap E is folded approximately 90 °C around folding line 3 and flap G is folded inwardly around folding line g to rest against the underlying flap E. Flap F is folded inwardly around folding line f, and the peripheral section F' is folded and inserted along the edge of flap G and flap E. Flap H is folded inwardly to rest against flap F, and the peripheral section H' is folded around folding line H' and inserted into locking position in slit B. At the other end of the container 12 a flap J is folded inwardly around folding line j, flap K is folded inwardly around the folding line k to rest against flap J and flap L with the handle N being folded inwardly around folding line I, and the flap's edge section L' is inserted between the far edges of the flap's J and K, and flap M i folded inwardly around the folding line m to rest against flap L, with the edge section M' inserted into locking position in a slit O, and with the handle N inserted into flap slit P. The container 12 is then ready for use.

When the container 12 is used for storage of waste, for instance used single use syringes, needles for syringes, used dressings etc., the opening Q in the container lid is exposed,

whereafter the waste is fed into the container through the opening Q, which is subsequently closed. The filled container with its contents may thereafter be transported for destruction by combustion in a suitable stove, or locally. In the latter case, the container is placed on its side, with the slit portion T facing upward, whereafter the slit T, by pulling the flap R is detached along the pre-cut and enclosing perforated lines, set on fire and fed into the open slit, so that both the container as well as its contents with possible contagious material is burned and rendered harmless.

The container may be supplied with instructions for use, other information and advertisements which are printed on the container surfaces, or on separate labels.

The safety box /combustion container according to the invention is preferably made from recycled quality sorted cardboard- and paper waste. In accordance with the above-mentioned specifications, it is assumed that the cardboard material has a combination of several layers in its laminate, and that the combination of these fulfils the specification's requirements for

- resistance against penetration from needle points,
- resistance against deformation caused by repeated drops/overturnings,
- internal absorption of fluid droplets (not specified),
- water resistant out of surfaces of the box,
- complete inflammability,
- sufficient strength in the box's handle and
- safely function covers for closing of the box's opening.

The box/container product is delivered flatly packed in one piece, thereby meeting the requirement for efficient transportation and storage. The product has been designed and completed with printed illustrations and instructions in the subject users' languages, so that the box can be assembled/mounted by unskilled personnel in approximately two minutes.

The opening Q for feeding of used syringes etc. and for subsequent closure, is designed so that the user, taking ordinary care, will be protected against his fingers coming into contact with needles points and against contamination through droplets.

The combined effect of the qualities from the materials chosen, and the construction of the box, is best signified when it is put on fire, achieving complete combustion of the box and its contents of waste. When the flap T is turn off, the thin, outer sheet paper is separated from the other laminate, at the same time as an opening in the box is formed. After being put on fire, for instance by use of a match or similar means, the burning paper sheet is fed through the opening, for setting fire to the waste in the box. The construction of the box will make it maintain its form for a sufficient period of time, to ensure satisfactory combustion of the box and its contents, which is clearly apparent from figs. 3 to 8. During the combustion process the layered bottom of the box will be successfully opened, and give new supply of air to the flames. Smouldering mass of plastic will delay the combustion, and keep the waste material gathered, for complete destruction. Filled safety boxes may also be discarded in available incinerators, thereby adding to maintaining the combustion.

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The outer cardboard, which provides for transportation of several safety boxes, is an important part of the product, and it may, due to a convenient choice of material and design, be used for collection of wet waste material, for instance used bandages, compresses and similar materials for subsequent destruction, for instance in an incinerator.

For the sake of giving a complete overview, it should be pointed out that the five litre safety box of the "POLYSAFE"-type as of February 1998 is the only product meeting the requirements according to the WHO Performance Specification E10/IC.1. A ten litre box, which meets the same above-mentioned requirements exists, that it comprises three different components, which must be assembled in correct sequence, and it is regarded as being less suitable due to high procurement-, transportation- and assembly costs. A five litre box according to the invention has undergone two different tests at Force Institute. The report from the institute are attached as exhibit 1 and 2, and the conclusion are, in average, as follow:

Testing of a five-litre container for syringes, type GLO 1.5 from Polynor AS at Force Institute on October 28, 1996. File no. 65788/m 1460-146. The testing was executed in accordance with WHO Standard Test Procedure E10/Proc/1 Rev. 11/95.

I. Testing of five litres syringes and combustion container, comprising

1.1	Product details
1.2	Instructions
1.3	Dimensions and weight
2.1	Convenience of filling
4.1	Needle penetration
4.2	Water resistance
4.3	Free fall, 60 – 80 cm

The container was delivered flatly packed. It was completed without problems in the course of two minutes, into a good box form, which easily could be handled by use of three fingers. 100 pcs. of syringes were easily fed into the container. It fulfilled the water resistance requirements without showing signs of water absorption. 70 free falls were completed without remarks. After 100 falls a weak deformation of bottom corners where noted. The sides of the side-bottom corners where cracked completely on its left side and on half the length of the right side. No needle points had penetrated the container walls during the fall test. As a conclusion from what has been stated above, it appears that the tested five litre container, type GLO 1.5, meets the requirement of WHO Standard Test Procedure E10/Proc/1 Rev. 11/95.

II. Flammable testing of five litres syringes container type GLO 1.5 from Polynor AS, February 9, 1998. File no. 91530/m 1460-190.C. The testing was executed in accordance with WHO Standard Test Procedure E10/Proc/1/Rev. 11/95, Clause 3, "fire- and combustion test". Conclusion: The container was easily inflammable, and the combustion take place in a satisfactory manner, until the container with its content and 100 pcs syringes had been completely combusted. No content escaped from the container during the combustion. 7 minutes after combustion, a temperature of 600 °C was measured in the middle of the amassment of syringes, and this temperature persisted for 13 minutes. The remaining waste materials after combustion consisted of ashes and needles, which were tarnished blue due to the high temperature.

From the above will be seen that the tested five litres container, type GLO 1.5, meets the requirement according to WHO Standard Test Procedure E10/Proc/1 Rev. 11/95. Clause 3.

The above-mentioned two tests show clearly that the described five litres safety box / combustion container, type GLO 1.5, according to the invention, is of a new, previously unknown type which is characterized in the particular construction, material and combinations outlined in the following claim.

The complete report from Force Institute regarding the two executed tests are attached for further information as Exhibits I and II.

## PATENT CLAIM

Safety box (combustion container) (12) in particular for temporary and risk free storage 1. of disposable contagious, surgical waste material, for instance used syringes with needles, discarded dressings, compresses etc. for subsequent destruction/combustion and made from a laminated substantially flat blank (10) from a resirculated and quality sorted paper/cardboard with printed instructions for used, arranged for fast and convenient assembly of the box and with stamped score lines for folding of a pluarity of side flaps (A-M), for the erecting of a safety box, the inside of witch is fluiddrops-absorbent and the outside is covered with a fluid-repellent coating, the box-overside having a closable orifice (q) for inserting of discarded surgical material etc... characterised in that the box is made of a material rendering durability against shock and deformation in case of falls or overturning, said material is easily inflammable, easily combustible, and one of the longer box-sides has an ignition opening, closed by a cover leaf (T) which may be torn off, set on fire and inserted through the ignition opening in the box, to set the box on fire; such ignition resulting in a complete combustion of the box including the waste contents, and that the box/container is of a unique type, presumably the only one, with a combined effect between material qualities and constructions details, in compliance with the requirements of WHO Performance Specification E 10/IC. 1 and E 10/IC.2.